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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,719	11/17/2003	Janel E. Young	ETH5095	2358

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ROBERTS MLOTKOWSKI SAFRAN & COLE, P.C.
Intellectual Property Department
P.O. Box 10064
MCLEAN, VA 22102-8064

EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
03/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

lgallaugher@rmsclaw.com
dbeltran@rmsclaw.com
bdiaz@rmsclaw.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/714,719	**Applicant(s)** YOUNG ET AL.	
	Examiner BLESSING M. FUBARA	**Art Unit** 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: Applicant traverses the combination of Sheffield with Adachi because Sheffield is a topical administration of NSAIDs and not tranilast. But, the combination was made in view of the teaching that drugs can be topically/locally administered to surgical sites to inhibit or treat adhesions so that it will be reasonably expected that tranilast can also be topically/locally administered to treat adhesions at the site of surgery. Topical/local administration of tranilast to surgical site would predictably effect inhibition of post surgical adhesion because tranilast is known to do that and topical/local administration of NSAID to surgical site inhibits adhesions at surgical site. In the current case, the motivation is to solve the problem of post surgical adhesions and oral and topical administrations are finite numbers of the processes that have been identified in the art of solving the problem. Therefore, the ordinary skilled artisan has good reason to pursue the known options in inhibiting post surgical adhesions. Because, topical administration of agents is known to inhibit post surgical adhesion, the topical administration of tranilast would lead the anticipated success of inhibiting post surgical adhesions. Therefore, because the topical administration of tranilast would lead to the anticipated success, it is likely that topical administration of tranilast is not innovative. See MPEP 2143. Therefore, applicant's citation of MPEP 2143 and the suggestion by the KSR court supports the rationale for topically applying tranilast at the surgical site to inhibit post surgical adhesions.
Applicant argues that topical efficacy cannot be predicted or even reasonably expected for tranilast. The examiner disagrees because it is known to inhibit post surgical adhesions by topical administration to surgical sites, it is also known that tranilast inhibits post surgical adhesions, thus, it would be reasonable to expect that tranilast can be administered by any of the known method to inhibit post surgical adhesions except there is reason to bar the topical administration of the tranilast. So far, applicant has not provided such a reason.
Applicant has compared data in Table 3, 12, 14, 15 and concludes that oral administration of tranilast is not effective for adhesion reduction and as such the data in Adachi is not enabled. The examiner begs to differ. Tables 2-4 in applicant's specification show effect of Tranilast as dose related with dose at 6.25 mg/mL tranilast showing the lower adhesion area percent and lowest adhesion tenacity. The data in at least Tables 6 and 9 (0.025 mg/ml), 7 and 10 (6.25 mg/ml) and 8 and 11(62.5 mg/ml) show that the length of time of administration has an effect on the percent area of adhesion and the tenacity of the adhesion, and also the mg/ml administered. These data in these tables are not commensurate with claim 1 that administers any amount of tranilast. These data are not also commensurate with claim 11 that administers tranilast at a range of 0.01 mg/kg to 3,000 mg/kg. Further, the comparison of Tables 13 and 16 (6.25 mg/mL and 60 mg/kg plus 6.25 mg/ml topical) and 13 and 14 (60/mg/kg) is not true comparison because there is no correlation between how much tranilast is administered locally and orally since the weight of the rabbit is not known and the volume of tranilast administered is not disclosed. This interpretation is supported by applicant's data in Tables 2-5 and 6-11 where it is shown that the effect of tranilast on adhesions is dose dependent and length of administration time dependent. At best the tables 13-16 show that the tenacity of adhesions in these cases is less than in the placebo case shown in Tables 5 and 12. Therefore, these data in applicant's specification do not show non-enablement of Adachi's claims that tranilast prevents postoperative intraperitoneal adhesions (title of Adachi) and reduced the frequencies and strength of adhesions (left column of page 54 of Adachi).

/BF/